

REMARKS

The Examiner is thanked for the due consideration given the application. This Amendment is being filed concurrently with a Request for Continued Examination. A Declaration is attached to this paper.

Claims 12-15, 17-29, 31 and 32 are pending in the application. Claims 12 and 13 are amended and claims 31 and 32 are newly presented. The amendments to the claim set find support in, e.g., Example 1 of the specification. Claim 28 has been withdrawn.

No new matter is believed to be added to the application by this amendment.

Statement of Substance of Interview

The Examiner is thanked for graciously conducting a personal interview with the Applicant's representative on February 5, 2009. During the interview the patentability of the present invention and the prior art was discussed, along with potential amendments to the claims and enablement issues. At the end of the interview, the Examiner prepared an Interview Summary. The Interview Summary has been reviewed, and it appears to accurately reflect the substance of the interview.

Rejection Under 35 USC §112, First Paragraph

Claims 12, 13, 17, 18 and 20-27 have been rejected under 35 USC §112, first paragraph as not being enabled. This rejection is respectfully traversed.

The Official Action asserts that the specification is enabling for processing fresh plasma but does not reasonably provide enablement for processing frozen plasma. The comments in the Official Action have been considered, and the claims have been appropriately amended without prejudice or disclaimer in order to expedite prosecution on the merits.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Rejections Based On JP 64-051075

Claims 12-16, 18-26, 29, and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over JP 64-051075. Claim 27 has been rejected under 35 U.S.C. 103(a) as being unpatentable over JP 64-051075 in view of JP 3-146067. These rejections are respectfully traversed.

The present invention pertains to a method for producing a plasma product that includes separating fresh plasma from whole blood, reducing leukocytes in the plasma, and filtering the plasma with a virus removing membrane.

Distinctions of the present invention over JP 64-051075 and JP 3-146067 have been made of record in the Amendment of

September 3, 2008. For brevity, these distinctions are not repeated here.

Supplemental to these distinctions, the Applicant has compared the present invention with that of the applied art by calculating the amount of treated plasma or the time necessary for the treatment based on a membrane area, and found that the present invention is effective in that the time necessary for the treatment is much shorter.

In the Example of JP 64-51075, ten thousand hollow fibers of 20 cm length for removing virus were bundled and formed into a module. There is no disclosure of a membrane area or an inner diameter of the module, but the inner diameter of the hollow fiber is disclosed to be 200-800 μm (page 4, right lower column, line 7). Based on this inner diameter, a membrane area of the module is calculated to be 1.3-5.0 m^2 .

Blood was introduced from a blood-inlet at a speed of 70 mL/min and plasma was made to run into a plasma flow channel at a speed of 20 mL/min, in a virus-removing device where the above module is used (Figure 1), thus treating 3 L of blood (page 8, left upper column, lines 1-3). Generally speaking about 70% of blood is plasma, so it is assumed that it took 105 minutes to treat 2.1 L of plasma. (The average pore size of the hollow fiber is disclosed to be 35 μm , which should read as 35 nm, considering the size of virus.)

On the other hand in the present invention, it took 30 minutes to filter 250 mL (0.25 L) of plasma by a virus-removing membrane which has an average pore size of 35 nm and a membrane area of 0.06 m².

As shown in below table, about 2.6 – 9.9 times the plasma can be treated in the same treatment time by the present method. Further for treating the same amount of plasma, the treatment time is shortened to 1/9 to 1/35 compared to that of the reference, 105 minutes.

	JP 64-51075	Present invention	A: <i>Assuming membrane area of the present invention to be same with that of the reference</i>	B: <i>Further assuming the amount of treated plasma to be same with that of the reference</i>
Amount of plasma (L)	2.1	0.25	5.5 – 20.8 2.6 to 9.9 times of plasma (compared to 2.1 L of reference) can be treated in 30 minutes.	2.1
Membrane area (m ²)	1.3 – 5.0	0.06	1.3 – 5.0	1.3 – 5.0
Treatment time (min)	105	30	30	12 – 13 Treatment time was shortened to 1/9 to 1/35 (compared to 105 minutes of reference) to treat same amount of plasma.

Notes: The amount of treated plasma was assumed to be in proportion to a membrane area (A in the table). Also the

amount of treated plasma was assumed to be in proportion to treatment time (B in the table).

These above observations showing unexpected results and the criticality of the steps, are re-presented in the attached Declaration.

One of ordinary skill and creativity would thus fail to produce a claimed embodiment of the present invention from a knowledge of JP 64-051075 or a combination of JP 64-051075 with JP 3-146067. A *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

The rejections have been overcome, obviated or rendered moot and no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item:

- Declaration by Tetsuo SATO